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Finite Element Lifetime Prediction of a Miniature Adjustable Orthopedic Device

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Abstract— **In Total Knee Arthroplasty (TKA), accurate balancing of the medial and lateral collateral ligaments is considered by orthopedic surgeons as one of the most challenging and complicated tasks to achieve. Therefore, an efficient solution is needed to assist the surgeons in achieving this crucial task without resulting in tibiofemoral misalignment. The required solution consists in developing either a completely automated smart ligament balancer for intraoperative use or adjustable tibial implant for postoperative use. The smart ligament balancer allows the surgeon to accurately balance the collateral ligaments at the time of surgery while the adjustable tibial implant can be controlled in the postoperative period in order to correct the residual ligament imbalance. In this paper, we propose a miniature device that can be used as a smart ligament balancer during TKA or as an adjustable tibial implant in the period following the surgery. Three designs of the smart ligament balancer have been developed using 3-Dimensional (3D) Computer Assisted Design (CAD) software. The proposed balancer can also be used as an adjustable tibial implant after slightly modifying its design. Finite element study of each design has been conducted in order to predict the lifetime of this implant in both cases of intraoperative or postoperative uses.**

I. INTRODUCTION

The importance of acquiring a proper ligament balance at the time of TKA is well recognized [1]. Many techniques have been used to assess the ligament balance during the operation. These techniques include the knee tensioning devices [2], spacer blocks [3], and manual distraction instruments. The aforementioned techniques balance the medial and lateral collateral ligaments by loading them either up to the maximum or in an uncontrolled way. If the resultant gap is trapezoidal, the achieved ligament balance is then imperfect. Moreover, the traditional tensors are unable to accurately assess the ligamentous balance because of the discrete measurement of tibiofemoral force [4]. A robotized distractor [5] has been developed to assess the soft tissue balance. This distractor consists of a baseplate assembled with two independent and parallel trays. The upper trays support the condyles and can be lifted by means of a jack and a cable or thanks to two inflatable rubber bladders. The disadvantage of the first approach of lifting is that the device is not powerful enough (maximal force is equal to $100\ N$) while the shortcoming of the second approach is that the parallelism of the upper trays cannot be assured; which influences the right functioning of the device. A force-sensing device [6] has also been developed to intraoperatively enhance the ligament balancing procedure. This device has two sensitive plates to support the two femoral condyles, a tibial baseplate to be positioned on the tibial cut surface, and a set of different size spacers to accommodate the apparatus thickness according to the patient-specific tibiofemoral space. Each of the two sensitive plates is instrumented with three deformable bridges. Each bridge is equipped with a thick-film piezoresistive sensor to ensure the accurate measurement of the amplitude and location of tibiofemoral contact force. The soft tissue imbalance is then assessed by the net varus/valgus moment. The major limitation of this device is that the load is manually applied by stressing the lower extremity. Therefore, it is difficult to accurately apply the desired load. Moreover, increasing the height of tibiofemoral gap and consequently tensioning the surrounding ligaments must be achieved by inserting different size spacers, which increases the time and complexity of TKA.

The aforementioned shortcomings in the devices intraoperatively used to balance the collateral ligaments raise the need for smart knee balancer that could accurately assess and achieve the ligament balance at the time of surgery. These shortcomings also raise the need for an adjustable tibial implant that could be implanted along with the other components of TKR in order to correct the residual ML ligament imbalance of the prosthetic knee postoperatively.

II. MATERIALS AND METHODS

A. *The* 3D *CAD model of the smart ligament balancer*

The intraoperative use of the smart knee balancer that we propose aims to accurately reestablish a rectangular tibiofemoral gap with symmetric MedioLateral (ML) load distribution across the whole range of passive knee flexion. On the other hand, the adjustable tibial implant could postoperatively be used to assess the ligamentous imbalance and restore the balance when needed.

A detailed 3D CAD model (Fig. 1) of the proposed device has been designed and developed under ANSYS DesignModeler tool (*ANSYS, Inc.*) in order to describe its operation [7]. The device consists of a fixed baseplate and two mobile plates. The lower baseplate is separately connected to each of the top plates by means of a scissor mechanism supposed to be operated by a miniature linear actuator. The actuator located at the bottom of the baseplate compartment is supposed to drive one sliding pin towards and away from the other in order to move the upper plate upwards and downwards (Fig. 1). The two actuators must automatically be driven by

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a microcontroller in response to the command signal sent by the surgeon and to the force and position values measured by adequate force and position sensors embedded within the device. Three force sensors must be embedded within each mobile plate to continuously measure the amplitude and location of the corresponding compartmental contact force. One position sensor must be embedded within each compartment of the baseplate to accurately measure the distance between each upper plate and the lower baseplate at any time of the balancing procedure.

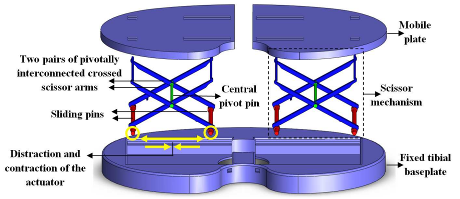


Fig. 1: An exploded view of the smart ligament balancer (α design)

The relationship between the force measured on the upper surface of the mobile plate and the force exerted by the corresponding actuator in order to expand or collapse the scissor mechanism and consequently the balancer is given by the following equation:

$$F_{Actuator} = \frac{F_{Condyle} + W + \left(\frac{W_{Arm}}{2}\right)}{Tan\left(\theta\right)} \tag{1}$$

where $F_{Actuator}$ is the force provided by the actuator arm, $F_{Condyle}$ is the force applied to the upper plate by the corresponding femoral condyle, W is the weight of the mobile plate, and W_{arm} is the combined weight of the two scissor arms (Fig. 2).

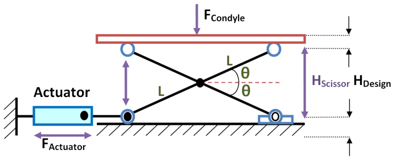


Fig. 2: Scissor lift jack

The height of the scissor mechanism can be obtained from the following relationship:

$$H_{Scissor} = 2 \cdot L \cdot \sin\left(\theta\right) \tag{2}$$

where $2 \cdot L$ is the length of scissor arm and θ is the angle between the horizontal and scissor arm. On the other hand, the overall height of the smart ligament balancer is given as follows:

$$H_{Balancer} = H_{Scissor} + H_{Design} \tag{3}$$

where H_{Design} is the design-specific height.

As shown in Fig. 3, the height of the α design when it is completely collapsed is equal to 7 mm while the fully expanded height is about 18 mm. The starting angle (θ_{Start}) must be chosen in such a manner that the balancer is completely collapsed with its initial and minimum height ($\theta_{Start} \cong 3.5°$ when $H_{Collapsed} = 7\ mm$) and the ending angle (θ_{End}) must not exceed a certain limit in order to maintain the parallelism of the upper plates and to ensure their stability with respect to the transverse plane ($\theta_{End} \cong 30°$). According to Eq. (2) and Eq. (3) and since the length of the scissor arm ($2{\cdot}L$) is 25 mm and the design-specific height (H_{Design}) is 5.5 mm, the balancer can expand to reach its maximum height ($H_{Expanded} = 18\ mm$) in a continuous movement.

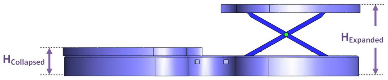


Fig. 3: The collapsed and expanded heights of the proposed balancer (α design)

B. Fatigue stress analysis of the proposed smart ligament balancer

Fatigue stress analysis of the α design of the proposed ligament balancer has been performed using FEA. As mentioned before, ANSYS DesignModeler tool (*ANSYS, Inc.*) was used to geometrically model the different parts of the balancer. Component meshing, processing, and postprocessing have been implemented using ANSYS Workbench 11 software (*ANSYS, Inc.*). The element type that has been chosen to mesh the structure was "SOLID187"; 10-node tetrahedral structural solid element. This type of element has a quadratic displacement behavior and is well suited to modeling irregular meshes (such as those produced from various CAD/CAM systems) [8]. The device is supposed to be made of Titanium alloy (*Ti-6Al-4V*) which is compatible with the human body and strain gauge technology. The material properties and fatigue data of this alloy have been extracted from the MIL-SPEC Handbook [9]. The contacts between the different parts of the ligament balancer were chosen as if the balancer is locked at a fixed position by the lead screw of the linear actuator supposed to be located within the tibial baseplate to drive the interior sliding pin of each scissor mechanism. The boundary conditions were defined in order to simulate the case where the two collateral ligaments are perfectly balanced. The tibial baseplate was fixed at its lower surface which must typically be positioned on the tibial cut. Two equal loads were applied downwards to both the upper plates in order to simulate either the tension of collateral ligaments at the time of surgery when the intraoperative use is inspected or the *in-vivo* force transmitted across the prosthetic knee when the postoperative use is inspected. Intraoperatively, the compressive load applied to each upper plate was equal to 100 N in order to ensure an adequate safety margin knowing that the passive loads acting through the tibiofemoral joint at the time of TKA are usually expected to change between 0 and 100 N maximum [6]. Postoperatively, the applied axial load was equal to 1300 N knowing that the peak tibiofemoral force transmitted via the prosthetic knee during the gait cycle is typically 2600 N [10]. In the case of an intraoperative use, the peak von Mises stress occurred at the posterior end of each sliding pin and more accurately at the contact point between this pin and the slot made in the cavity of tibial baseplate to receive the pin end was approximately 778.2 MPa (Fig. 4-a). The expected minimum life of this model before the failure of the sliding pins was 8.3×10^6 $cycles$. In the case of a postoperative use, the peak von Mises stress occurred at the same point of sliding pins (Fig. 4-b) and was equal to 10116 MPa. Furthermore, this weakest point of the structure was predicted to fail after only one load cycle. Therefore, the design of ligament balancer for postoperative use must be optimized in order to meet the TKR lifespan.

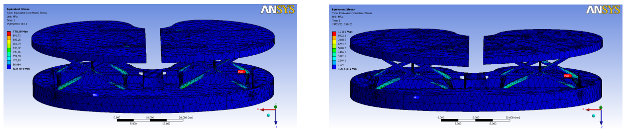

(a) Intraoperative use (b) Postoperative use

Fig. 4: Equivalent von Mises stress in the critical area of the α design

C. Design Optimization

In order to avoid the fatigue failure of the different parts of the smart knee balancer proposed to postoperatively correct the residual ligament imbalance besides its intraoperative use, two further designs (β and γ designs) have been developed from the previously studied design (α design). The objective of developing these two designs (Fig. 5) is to optimize the α design in such a manner that the expanded balancer can withstand the repeated cyclic loading exerted by the prosthetic femoral condyles and transmitted through the UHMWPE insert to its upper plates during normal walking. Given that the optimum design life of the aforesaid balancer is equal to 10^9 $cycles$. Since the most active patient undergoing a TKA procedure may perform more than 3.5 $times$ the average number of cycles walked per year (0.9×10^6 $cycles$ per year) [11] and due to the fact that the 10 to 15 $years$ survival rate of TKA has improved to approximately 95% [12], the number of gait cycles performed by an active patient during 15 $years$ is about 47.3×10^6 $cycles$. In this case, the studied design life of the smart knee balancer is approximately 21 $times$ greater than the longevity of TKR in the best of cases.

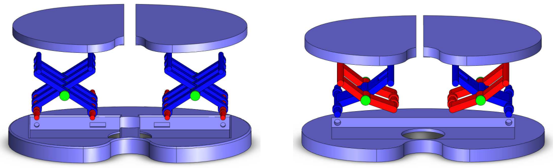

(a) β design (b) γ design

Fig. 5: An exploded view of the smart ligament balancer (β and γ designs)

In the β design, the external pins were pivoted while the internal pins were allowed to slide towards and away from the pivot ones. The diameter of each pin was increased compared to that in the α design. In addition, three pairs of pivotally interconnected crossed scissor arms were used in the mechanism of β design instead of two pairs in that of α design in order to support the peak axial force transmitted through the prosthetic components during the gait cycle. Moreover, the contact points between the pivot and sliding pins of the scissor mechanisms, on the one hand, and the cavity of the tibial baseplate, on the other hand, were increased in order to distribute the axial force transmitted through the mechanisms to the tibial baseplate. The peak von Mises stress for this design was concentrated at the contact point between the mobile tray and the scissor arm connected to the pivot pin (Fig. 6). This peak was equal to 126.7 MPa in the case of an intraoperative use and to 1647.3 MPa in the case of a postoperative use. The minimum predicted fatigue life of the intraoperative balancer was equal to 8.3×10^6 $cycles$ against 71811 $cycles$ of normal walking for the postoperative use of this device.

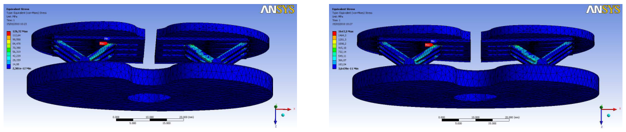

(a) Intraoperative use (b) Postoperative use

Fig. 6: Equivalent von Mises stress in the critical area of the β design

The scissor mechanism of the γ design was completely different from those of the α and β designs in order to better resist the excessive loading conditions in other activities of daily living such as the stair climbing and descending, kneeling, and rising from a chair. In this design, the maximum von Mises stress was focused at the contact points between the sliding pins and the tibial baseplate (Fig. 7). This equivalent stress was equal to 105.1 MPa intraoperatively and to 1366 MPa postoperatively while the minimum fatigue life was found to be 8.3×10^6 $cycles$ of intraoperative use and 4.5×10^5 $cycles$ of postoperative one.

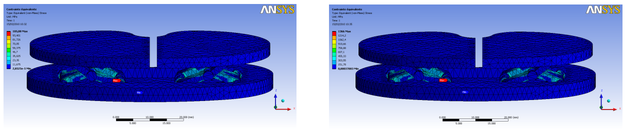

(a) Intraoperative use (b) Postoperative use

Fig. 7: Equivalent von Mises stress in the critical area of the γ design

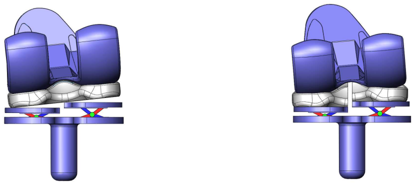
The comparison among the three aforementioned designs of smart knee balancer is shown in Tab. I.

The smart knee balancer for postoperative use is supposed to replace the tibial component of a fixed-bearing TKR and is therefore referred to as an adjustable tibial implant. In this situation and due to the fact that the full contact between

TABLE I: Comparison among the different designs of smart knee balancer

	α design	**β design**	**γ design**
Collapsed height $[mm]$	7	7	7
Expanded height $[mm]$	18	17	13
Weakest point	Sliding pin	Mobile tray	Sliding pin
Peak von Mises stress for intraoperative use $[MPa]$	778.2	126.7	105.1
Peak von Mises stress for postoperative use $[MPa]$	10116	1647.3	1366
Minimum predicted life for intraoperative use $[Cycles]$	8.3×10^6	8.3×10^6	8.3×10^6
Minimum predicted life for postoperative use $[Cycles]$	1	71811	4.5×10^5

the upper surfaces of the two mobile plates and the lower surface of the UHMWPE insert will not be maintained (Fig. 8-a) because of moving one mobile plate relative to the other when rebalancing the collateral ligaments, the UHMWPE lower surface would easily wear out. Let us suppose that the UHMWPE insert can be partitioned into two equal inserts (Fig. 8-b), one for each mobile plate. In this case, the relative movement of one mobile plate with respect to the other will influence the conformity between the prosthetic femoral condyles, from one side, and the upper surfaces of the UHMWPE inserts, from the other, and accordingly the stress would be concentrated in small contact areas; which in turn accelerates the wear mechanism of UHMWPE insert.



(a) One UHMWPE insert (b) Two UHMWPE inserts

Fig. 8: Smart knee balancer assembled with TKR

According to what has been mentioned above, the postoperative utilization of the adjustable knee implant with two mobile plates is impossible. Therefore, another 3D CAD model of this implant with only one mobile plate has been designed in order to address the postoperative needs (Fig. 9). The new design is composed of a fixed baseplate, two scissor lifting mechanisms; one in the medial compartment of tibial baseplate and another in the lateral one, and a mobile plate connected to the baseplate by means of the two lifting mechanisms.

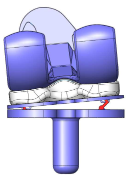


Fig. 9: The adjustable knee implant for postoperative use (right knee)

III. CONCLUSION

In this paper, we proposed three possible designs of a miniature orthopedic device that can be embedded within the tibial component of TKR in order to adjust the height and inclination of an intermediate plate with respect to the tibial baseplate. The objective of this mechanism is to correct the ligament imbalance intra- and/or postoperatively through the full range of knee motion when needed. 3D CAD model of each design has been developed in order to achieve a finite element static structural analysis that allows us to estimate the predicted lifetime of each design in case of both intra-operative and postoperative uses. As we have seen earlier in this paper, only the γ design fulfills the long lifetime expectations in case of both uses of the proposed device. The actuator supposed to drive the adjustable mechanism is now under research and development in our laboratory.

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